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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,921	05/13/1999	GUNTER DONN	514413-3669	9327

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EXAMINER

BRUNOVSKIS, PETER

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 11/23/2001

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/155,921	DONN ET AL.	
	Examiner	Art Unit	
	Peter Brunovskis	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1638.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicants are directed to the enclosed CRF Problem Report, which indicates that the previously submitted CRF was damaged. To avoid irradiation-induced damage to subsequently submitted CRFs, please submit them directly to the Arlington addresses listed on that report.

Applicants' amendments of 6 June 2002, and accompanying arguments and declaration, have overcome the following: the objections to the specification and claims, and the rejections under 35 USC 112, second paragraph, except as indicated below.

Claims 9 and 11-16 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims remain rejected for the failure to positively recite a required claim element, namely the recovery of plants *with improved growth characteristics*, in the body of the claims, as stated on page 3 of the last office action, penultimate paragraph. Applicants' amendments to the claims to overcome the other indefiniteness rejections are acknowledged.

Claims 14-16 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 9-10 of the last office action.

Claims 9 and 11-16 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a construct comprising an E. coli ammonium-specific asparagine synthase type A gene ligated to a chloroplast transport-encoding sequence, and plant cells and plants transformed therewith, does not reasonably provide enablement for claims broadly drawn to any other asparagine synthase genes from any other source. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 10-12 of the last office action.

Claims 9, 11-13 and 16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Coruzzi et al (AG) in view of Dudits et al (AH), Temple et al (AP) and Della-Cioppa et al, as stated in the last office action on pages 12-17.

No claim is allowed.

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Applicants' arguments filed 6 June 2002, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicants urge that the rejections under 35 USC 112, first paragraph, are improper, given the enabling disclosure of the fusion of the pea RUBISCO transit peptide, the ability of the skilled artisan to select another transit peptide from another source, and the ability of the skilled artisan to identify and isolate other asparagine synthase genes as suggested by the specification.

The Examiner maintains that claims 14-16 were rejected under the written description requirement. The claims encompass a multitude of duplicated 20 base pair regions anywhere in the pea RUBISCO transit peptide-encoding sequence, while the specification only provides a description for the duplication of a single 20 base pair region. The enablement of other native transit peptide encoding sequences is not an issue.

With regard to the enablement of asparagine synthase genes other than the *E. coli* ammonium-specific type A asparagine synthase gene, the Examiner maintains that the existence of other such enzymes or genes is unpredictable. Furthermore, the Examiner has provided scientific reasoning to support his position that the behavior of such genes in transformed plants for the obtention of enhanced growth is unpredictable. It is noted that claims 9 and 11 are not limited to an ammonium-specific asparagine synthase. Finally, Applicants' assertions regarding the existence of other asparagine synthase proteins from other sources are not probative. See In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 USPQ2d, 1210 (Fed. Cir.

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1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein.

Applicants urge that the art rejection is improper, given the limitation of the amended claims to the reduction in chloroplastic glutamine synthase and the disclosure in the instant specification of same, the lack of motivation to combine the cited prior art, and the failure of the prior art to teach or reasonably suggest the unexpected result of enhanced plant growth.

The Examiner maintains that the cited prior art provides ample suggestions to combine their teachings, including chloroplastic glutamine synthase genes, as stated in the last office action on pages 15-17.

Regarding the alleged unexpected results, the Examiner notes that Coruzzi et al teach enhanced plant growth following transformation with a gene encoding wild-type or mutated (ammonium-specific) asparagine synthase (see, e.g., pages 69-76), as did Dudits et al (see, e.g., pages 9-10). Furthermore, Applicants' actual results are difficult to ascertain. Other than an anecdotal statement bridging pages 19 and 20 of the specification, the only data demonstrating enhanced growth refer to enhanced growth of a single storage organ, namely a tuber, in a single plant species, namely potato, containing only the *E. coli* ammonium-specific asparagine synthase gene ligated to a chloroplast transit peptide-encoding sequence. There is no demonstration that plants also containing an antisense glutamine synthase gene showed any growth enhancement.

Furthermore, see In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be

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commensurate with the scope of the claims. The claims are broadly drawn to any asparagine synthase gene from any prokaryotic source (claims 9 and 11-16), including those genes not encoding an ammonium-specific asparagine synthase (claims 9 and 11-12), any duplication of any 20 base pair region of the RUBISCO transit peptide-encoding sequence (claim 14 and dependents), and any "portion" of any length of any glutamine synthase gene in antisense orientation. In contrast, Applicants' evidence of unexpected results depends upon a single bacterial source of the asparagine synthase gene which encodes an ammonium-specific enzyme, a single duplication of the pea RUBISCO transit peptide-encoding region, and optionally a full-length glutamine synthase gene in antisense orientation. It is also noted that claims 13-16 do not recite the presence of any antisense glutamine synthase construct, so that Applicants' arguments regarding the failure of the cited references to teach such an antisense construct are moot with respect to these claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 19, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

